UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 12, 2019

KRYSTAL BIOTECH, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38210**	**82-1080209**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

2100 Wharton Street, Suite 701
Pittsburgh, Pennsylvania 15203
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (412) 586-5830

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operation and Financial Condition.

On March 12, 2019, Krystal Biotech, Inc., a Delaware corporation (the "Company"), announced its fiscal year 2018 financial results. A copy of the Company's press release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

The information concerning financial results in this Form 8-K and in Exhibit 99.1 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information concerning financial results in this Form 8-K and in Exhibit 99.1 shall not be incorporated into any registration statement or other document filed with the Securities and Exchange Commission by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 12, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 12, 2019

KRYSTAL BIOTECH, INC.

By: /s/ Krish S. Krishnan
Name: Krish S. Krishnan
Title: President and Chief Executive Officer

Exhibit 99.1

Krystal Biotech Reports 2018 Financial Results and Business Progress

Topline-data from Phase 1/2 clinical trial of KB103 (bercolagene telserpavec) for treatment dystrophic epidermolysis bullosa (DEB) to be announced in 1H 2019

Ancoris, a cGMP facility for clinical and commercial production of KB103, is operational following successful completion of a trial run.

Planned filing of an IND for KB105 to treat autosomal recessive congenital ichthyosis (ARCI) in 1H 2019

Company was granted second patent for compositions containing KB103, formulated for alternate routes of administration

PITTSBURGH, March 12, 2019 – Krystal Biotech, Inc., ("Krystal") (NASDAQ: KRYS), a gene therapy company developing medicines to treat dermatological diseases announced financial results for 2018 and an update on its business progress.

Commenting on the year, Krish S. Krishnan, chairman and chief executive officer, said, "2018 was a productive year for Krystal as we worked to become fully-integrated in the gene therapy space. On the clinical front, we announced positive interim results on two adult patients from the placebo-controlled GEM-1 study of KB103 in October, and the completion of dosing of the remaining four, adult and pediatric patients in the study in December. On the manufacturing front, we recently inaugurated the Ancoris cGMP facility following a successful trial run, for the exclusive clinical and potential commercial production of KB103. On the platform front, we have started to demonstrate the viability of our platform beyond rare skin diseases as we expand into broad skin diseases and aesthetic skin conditions."

Mr. Krishnan continued, "Our top four priorities in 2019 are to commence the pivotal study of KB103 following completion of the Phase 1/2 GEM-1 study, initiate a Phase 1/2 clinical study of our second rare disease therapy, KB105, file an IND on an additional pipeline product, yet to be disclosed and begin work on our second, larger cGMP facility in Pittsburgh, to fully serve the production needs of our pipeline products."

2018 and Recent Corporate Highlights

- On March 5, 2019, we had the official inauguration of Ancoris, a commercial scale cGMP-compliant manufacturing facility, following completion of a manufacturing trial run of KB103.
- On December 18, 2018 the United States Patent and Trademark Office (USPTO) granted U.S. Patent No. 10,155,106 which covers compositions containing KB103, formulated for alternate routes of administration.
- On October 23, 2018, we announced the closing of a public offering of common stock and exercise in full of underwriters' over-allotment option. The gross proceeds to the

Company from this offering were $69.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

- On October 15, 2018, we announced positive interim results from a placebo-controlled Phase 1/2 clinical study of KB103 in adults with the rare skin disease dystrophic epidermolysis bullosa (DEB).
- On August 7, 2018, the FDA granted orphan drug and rare pediatric disease designation to our second product candidate, KB105, which is currently in preclinical development for treatment of patients with deficient autosomal recessive congenital ichthyosis (ARCI), which is associated with transglutaminase 1 (TGM-1). There are currently no treatments for this disease which affects approximately 20,000 patients worldwide. We anticipate filing an Investigational New Drug (IND) application for KB105 in the first half of 2019. The IND filing is a few months later than originally planned, following a scheduling issue at one of our third-party manufacturing vendors. All pre-clinical studies required for the filing of the IND have been completed.

Financial results for the year ended December 31, 2018

- Cash, cash equivalents and short-term investments totaled $111.8 million on December 31, 2018.
- Research and development expenses for the year ended December 31, 2018 were $7.8 million, compared to $3.2 million for 2017.
- General and administrative expenses for the year were $4.2 million, compared to $1.6 million for 2017.
- Net losses for the years ended December 31, 2018 and 2017 were $10.9 million and $7.9 million or ($0.97) and ($1.48) per common share (basic and diluted), respectively.

For additional information on the Company's financial results for the year ended December 31, 2018, refer to form 10K filed with the SEC.

About Krystal Biotech

Krystal Biotech, Inc. (NASDAQ:KRYS) is a gene therapy company dedicated to developing and commercializing novel treatments for patients suffering from dermatological diseases. For more information, please visit http://www.krystalbio.com.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding our intention to commence a pivotal study of KB103 in 2019, our ability to manufacture all needed clinical trial quantities of KB103 in our Ancoris manufacturing facility and to begin work on a second, larger manufacturing facility, our plans to file an IND for KB105 in the first half of 2019 and to file a second IND for an additional pipeline product in 2019. You can identify forward-looking statements because they contain words such as "believes" and "expects." Forward-looking statements are based on Krystal's current expectations and assumptions. Because forward-looking statements relate to the

future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees nor assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Krystal's filings with the Securities and Exchange Commission, including its registration statement on Form S-1 and Form 10-K, as amended from time to time, under the caption "Risk Factors."

CONTACTS:

Investors:
Ashley R. Robinson
LifeSci Advisors
arr@lifesciadvisors.com

Media:
Darren Opland, PhD
LifeSci Public Relations
darren@lifescipublicrelations.com

Source: Krystal Biotech, Inc.